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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/685,139

10/14/2003

Steve Mitchell

KLYC-1075US1

4489

7590

05/16/2006

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EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/685,139

Applicant(s)

MITCHELL, STEVE

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 70-76 and 78-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-69 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/1/2006 has been entered.

Specification

The abstract of the disclosure is objected to because the abstract contains phrases which can be implied, such as "the present invention...". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13-26, 30-43, 47-58, and 62-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose an implant comprising a body/base (FIG.1, ref. #22), at least one hook/flange extending from the body capable of allowing the body to engage a vertebra (FIG. 1, ref. #30 and #50), a beam extending from the body (FIG. 8, ref. #90), the beam having a distal end that can contact a spinous process of another vertebra, and a device that secures the beam to the body (FIG. 8, ref. #80). The beam extends beyond the body and extends beyond the hook (in the vertical direction). The device secures the beam to the body in a plurality of positions (col. 5, lines 31-46). The distal end of the beam, the spacer, is bulbous and is round (FIG. 8, ref. #90). The beam includes an elongated aperture (FIG. 8, ref. # 92). The elongated aperture of the beam receives a post extending from the base (FIG. 8, ref. #80). A lock cooperates with the post of the base to secure the beam to the base (FIG. 1, ref. #82). The device extends through the aperture and can be secured to the aperture in a plurality of positions in order to position the beam relative to the body in a plurality of positions (col. 5, lines 31-46). The body includes a first portion and a second portion (FIG. 2, ref. #32 and #52) with a beam platform located between the first and second portions (FIG. 1, ref. #70). There is a space between the platform and first and second portions. The hook extends from the first portion and another hook extends from the second portion. The device extends from the platform. The implant comprises a device that is capable of securing

the base to an S1 vertebra (FIG. 2, ref. #72). The spacer (FIG. 8, top end part of ref. #90) has a first end capable of contacting the spinous process of a first vertebrae without being attached to the spinous process of the first vertebrae, and a beam extending from the first end (FIG. 8, ref. #90). The beam is capable of being mounted to the base, or body, (ref. #22) and the base is capable of being mounted to a second vertebrae. The distal end of the beam provides a surface that is at an angle to the beam. The surface is capable of engaging L5 vertebra. The surface that is capable of spreading a contact load between a L5 vertebra and the distal end. The distal end of the beam is capable of engaging a spinous process of a L5 vertebra without being attached to a second vertebra. The distal end of the beam is capable of engaging a spinous process of a L5 vertebra over a conforming contact area. The implant is capable of being positioned between the S1 and L5 vertebrae, without being attached to the L5 vertebra. The distal end of the beam includes a convex surface (FIG. 8, ref. #90) that is capable of engaging a spinous process of a L5 vertebra in order to spread the load between the distal end of the beam and the spinous process of the L5 vertebrae.

With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Lee et al. which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA

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1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 27-29, 44-46, and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose the claimed invention except for the implant being made from a material such as polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct at least a part of the device of Lee et al. from a material such as polyetheretherketone, polyaryletheretherketone, polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium, since it has been held to be within the general skill of a

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worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed 5/1/2006 have been fully considered but they are not persuasive.

In response to Applicant's argument that the Lee et al. patent does not disclose "the beam extends beyond the body, wherein the beam extends beyond the hook", the examiner respectfully disagrees. The Lee et al. reference clearly shows that the beam/spacer component (ref. #90) extends in a vertical direction beyond the hooks/flanges (ref. #30 and #50) and the body/base (ref. #22), see Fig. 8. The examiner believes that the amendments to the claims are not sufficient to overcome the Lee et al. reference.

Regarding applicant's argument for the withdraw of the 103(a) rejections since they depend from the amended claims 1, 7, 9, 26, 43, and 58, the Examiner asserts that the rejections are still proper because the amended claims 9, 26, 43, and 58 are still rejected under 102(b) as explained above.

Therefore, the rejections under 35 U.S.C. 102(b) and 103(a) are deemed proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER